UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 16-2738 (MAS) (RLS)**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM IN OPPOSITION TO JOHNSON & JOHNSON AND LLT MANAGEMENT LLC'S MOTION TO EXCLUDE PLAINTIFFS' EXPERTS' OPINIONS REGARDING ALLEGED HEAVY METALS AND FRAGRANCES IN JOHNSON'S BABY POWDER AND SHOWER TO SHOWER

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The Plaintiffs' Steering Committee ("PSC") submits this Memorandum of Law in response and opposition to *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s*[1] *Motion to Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower to Shower.* For the foregoing reasons, this Court should deny Defendants' motion.

I. INTRODUCTION AND BACKGROUND

A. Amended Rule 702 does not fundamentally alter the requirements for admissibility of expert evidence.

Despite Defendants' assertion, the amendments to Federal Rule 702 did not change the requirements for expert admissibility.[2] The *Daubert* factors and the standard for admissibility remain the same, and Plaintiffs' experts on the topics of heavy metals and fragrances continue to ably meet that standard.

B. J&J's Talcum Powder Products are mixtures of numerous carcinogenic components, including heavy metals, fragrance chemicals, and fibrous talc.

J&J's Talcum Powder Products are not "pure." *Johnson's Baby Powder* and *Shower to Shower*[3] are *mixtures* of numerous constituents, including platy and

[1] Collectively referred to as "J&J" or "Defendants."
[2] *See* Plaintiffs' Steering Committee's Brief Regarding the Rule 702 Standard.
[3] Referred to herein as "Talcum Powder Products" or "Products."

fibrous talc,[4] asbestos, heavy metals, and fragrance chemicals.[5] Several of these constituents are established human carcinogens, including asbestos, fibrous talc, and the metals nickel and chromium (VI).[6] This opposition sets forth the PSC's opposition to J&J's challenges to the PSC's experts' opinions regarding two components of the Talcum Powder Products – heavy metals (chromium, nickel and cobalt) and the fragrances within the products (themselves mixtures of hundreds of chemicals).

C. J&J's Talcum Powder Products contain heavy metals, including known human carcinogens chromium and nickel.

The heavy metals nickel and chromium (VI) are human carcinogens.[7] Nickel, chromium (VI), chromium (III), and cobalt are all inflammatory agents.[8] The PSC's

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[4] IARC Monographs evaluate the carcinogenicity of talc and acrylonitrile, IARC Monographs Volume 136, Questions & Answers (Q&A), at 5 (July 5, 2024) (citations omitted) (emphasis added), attached as **Exhibit 1.**

[5] *See* May 28, 2024 Third Amended Report of Laura M. Plunkett, Ph.D., DABT ("Plunkett Report") at 18, attached as **Exhibit 2**.

[6] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 100C, Arsenic, Metals, Fibres, and Dusts (2012), relevant excerpts attached as **Exhibit 3 (Introduction and Preamble); Exhibit 4 (Nickel); and Exhibit 5 (Chromium).** *See also The Plaintiff Steering Committee's Opposition to Defendants' Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions.* J&J's fragrance is a mixture unto itself – the fragrance in Baby Powder is comprised of 141 constituents (some of which are themselves a mixture of chemicals) and the fragrance in Shower to Shower is comprised of 53 constituents.

[7] IARC, 2012 (**Exhibits 4 and 5)**

[8] *Id*. *See also* IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 86, Cobalt in Hard Metals and Cobalt Sulfate, Gallium Arsenide, Indium Phosphide and Vanadium Pentoxide (2006), relevant excerpts attached as **Exhibit 6**.

experts opine that these known carcinogens and/or inflammatory agents contribute to the inflammatory properties of the Talcum Powder Products, thereby playing a role in in the biologically plausible mechanism – inflammation – by which the Talcum Powder Products cause ovarian cancer. Defendants largely ignore the PSC's experts' testimony about biological plausibility, instead arguing that it was necessary to consider dose response and thresholds of exposure to the individual metals in the products. For the reasons discussed in more detail below, Defendants' argument is without merit – neither Bradford Hill nor the EPA's guidance on qualitative analyses of mixtures requires dose assessments of the individual constituents in a mixed product. The PSC and its experts allege the Talcum Powder Products as *a whole* cause ovarian cancer, with the constituent parts playing a contributing role.

It is beyond dispute that chromium, nickel, and cobalt are present in the Talcum Powder Products. J&J's own internal documents and tests establish that the heavy metals are 1) present in the Vermont mines that were used to source the Talcum Powder Products for decades, and 2) present in the finished products as well.[9]

[9] *See* **Exhibit 7**, JNJ 000237076 (showing two Grade 66 samples from the Hammondsville mine in Vermont in 1991 contained high levels of chromium, cobalt and nickel); **Exhibit 8**, IMERYS 342524 (showing high levels of chromium, cobalt, and nickel in a 1997 annual composite sample of Grade 66 talc as measured using two different testing methods). Testimony from Imerys Talc America, Inc. employee Ms. Julie Pier establishes that testing was done on samples of finished products, *see* September 12–13, 2018 Deposition of Julie Pier ("Pier Dep."), attached as **Exhibit 9** at 199:18–200:7 ("Q. A yearly composit of the ore is made from each individual submission to be tested for metals. . .? . . .[I]ts on a yearly basis after the product is

Defendants cannot plausibly dispute that the heavy metals are present, and instead argue that the PSC's experts "improperly interpret the literature" showing that the constituent heavy metals and fragrances in their products cause cancer.[10] Defendants further claim Plaintiffs' experts fail to establish a link between heavy metal exposure and the fragrances in Talcum Powder Products and ovarian cancer. But they do, and Defendants' attempt to convert scientific evidence into "speculation and innuendo" should be rejected.

D. The secret chemical in J&J's Talcum Powder Product fragrances are not in compliance with regulatory standards and contribute to the inflammatory properties, toxicity, and carcinogenicity of the products as a whole.

J&J *Baby Powder* is known for its distinctive scent. Yet this famous scent is nothing more than a mixture of chemicals. The FDA does not require companies to disclose the constituent chemicals in cosmetic fragrances to consumers, and J&J has therefore never revealed the identities of the chemicals in *Baby Powder* and *Shower*

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made."); Pier Dep. at 203:7–9 ("...there is post-finished-product testing as well by all of the methods, the XRD, PLM and TEM."); Pier Dep. at 413:5–7 ("Samples were taken...using...an automatic sampler while the silos are being filled of finished product."); Pier Dep. at 545:7–10 ("The quarterly finished product was from Vermont, and the finished product would have been Grade 66. Those were quarterly samples at that time."). For a more thorough recitation of test results, see the November 16, 2018 Expert Report of Robert Cook, Ph.D. ("Cook Report"), attached as **Exhibit 10**, and the November 16, 2018 Expert Report of Mark Krekeler, Ph.D. ("Krekeler Report"), attached as **Exhibit 11.**

[10] *See* Def. Memo. in Support, at 20.

to Shower fragrance.[11]

To complicate things further, some of those chemicals are themselves mixtures of *other* chemicals.[12] J&J's documents also reveal that there have been changes to the fragrance formulas over the decades – for example, Benzene, ethenyl- (more commonly known as styrene) was a chemical used in the *Baby Powder* fragrance formula until J&J removed it in 2014.[13] As discussed in more detail below, styrene was long classified by IARC as a 2B carcinogen—meaning it was *possibly* carcinogenic to humans. Today, styrene is classified as a 2A carcinogen—it is a *probable* human carcinogen.[14] J&J did not provide information regarding the precise quantities of each chemical in the fragrances, nor has J&J clarified whether the quantities of each chemical changed over the decade that the products have been sold to consumers.

The PSC's expert Dr. Michael Crowley offers two opinions about the Talcum Powder Product fragrance chemicals in this litigation: 1) they are not in compliance with government and industry standards (in other words, they raise regulatory concerns); and 2) the chemicals contribute to the inflammatory properties, toxicity,

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[11] *See* November 12, 2018 Expert Report of Michael M. Crowley, Ph.D. ("Crowley Report") at 12, attached as **Exhibit 12.**
[12] *Id.* at 12.
[13] *Id.* at 20.
[14] *See* **Exhibit 13**, Agents Classified by the IARC Monographs, Vols. 1–123, CAS No. 100-42-5 Styrene (2019) (IARC 2A classification for styrene).

and potential carcinogenicity of the Talcum Powder Products as a whole.[15] Dr. Crowley conducted an exhaustive review of the available safety data and studies for each chemical in the fragrances and recorded the data in his report. He relies on his own education and extensive experience as a chemist who creates chemical formulations for use in consumer products to reach his opinions in this litigation. Despite his thorough review of the totality of evidence and his relevant experience in the field of chemical formulation, Defendants argue that his opinions "lack good grounds," that they are unreliable because of a lack of studies linking the chemicals to *human ovarian* cancer specifically, and because he did not consider dose response. All of these arguments are without merit for the reasons set forth in this opposition.

II. ARGUMENT

A. Plaintiffs' experts are exceptionally qualified and rely on credible evidence that Talcum Powder Products contain carcinogenic heavy metals and fragrances.

Defendants challenge the qualifications of several experts to opine on heavy metals and fragrances found in talcum powder products.[16] They maintain that because the experts performed no independent analysis and lack the expertise to do

[15] Crowley Report at 12.

[16] These experts include Drs. Carson, Clarke-Pearson, Cook, Cote, Kane, Krekeler, Levy, McTiernan, Moorman, Plunkett, Sage, Siemiatycki, Singh, Smith, Smith-Bindman, and Wolf.

so, their opinions on these substances improperly parrot other experts' conclusions.[17] These criticisms lack merit.

1. The experts are qualified to offer general causation, biological plausibility, mining, and regulatory opinions.

Defendants' insistence that the PSC's experts "outstrip their relevant expertise" rests on a misapprehension of their opinions. The experts simply observe that they have reviewed evidence revealing the presence of heavy metals and fragrance chemicals in the Talcum Powder Products and the carcinogenic and inflammatory properties of such substances. These observations are made as predicates to the experts' ultimate conclusions on general causation, biologic plausibility, the mining process, and regulatory standards.

Drs. Carson, Clarke-Pearson, Cote, Kane, Levy, McTiernan, Moorman, Plunkett,[18] Siemiatycki, Singh, Smith, Smith-Bindman, and Wolf make these observations in furtherance and within the scope of their biological plausibility

[17] Def. Memo. in Support, at 8–9, 14, ECF No. 33005-2.

[18] Dr. Plunkett provides a risk assessment, which is different from a general causation analysis, but entails consideration of the same types of evidence. See December 19, 2018 Deposition of Laura Plunkett, Ph.D., DABT ("Plunkett Dep.") at 35:3–37:19, attached as **Exhibit 14**. As part of her risk assessment, Dr. Plunkett provides "opinions on certain aspects of the cause-and-effect relationship," including biologic plausibility and "underlying knowledge about different toxicities of the compounds." *Id*. at 33:19–34:9.

assessments.[19] These witnesses have specialized expertise in the fields of medicine, toxicology, gynecologic-oncology, epidemiology, pathology, biochemistry, microbiology, pharmacology, and chemistry qualifying them to opine on biological plausibility,[20] *i.e.*, whether the association between Talcum Powder Products and ovarian cancer is biologically plausible and consistent with existing scientific knowledge.[21] This inquiry requires the "experts to survey all the available evidence that might support or disprove causation."[22] Because the Products at issue are mixtures of several constituents, including platy talc, fibrous talc, asbestos, heavy metals, and fragrance chemicals,[23] the experts considered the totality of evidence regarding the routes of exposure by which the Talcum Powder Products could reach the ovaries, the potential mechanisms of carcinogenesis, the composition of the products, and the biological and toxicological effects of the products and their constituent parts. Based on their review, the experts observe that evidence reveals the presence of heavy metals and fragrance chemicals in the Products and the

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[19] *See The Plaintiffs' Steering Committee's Memorandum of Law in Opposition to Defendants Johnson & Johnson and LLT Management LLC's Motion to Exclude Plaintiffs' General Causation Opinions* ("PSC Gen. Causation Opp.").

[20] Indeed, Defendants do not challenge that these witnesses are qualified to render their general causation and biological plausibility opinions.

[21] *See* MICHAEL D. GREEN ET AL., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 549, 604 (Fed. Jud. Ctr. 3d ed. 2011).

[22] *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1130 (N.D. Cal. 2018).

[23] *See* Plunkett Report at 19.

carcinogenic and inflammatory properties of such substances, which further supports biological plausibility.[24]

Although Defendants argue that Drs. Mark Krekeler and Robert Cook lack the biological or medical expertise necessary to opine on whether heavy metals are human carcinogens, their opinions are also within the scope of their relevant expertise in the fields of geology and minerology. Drs. Krekeler and Cook do not provide medical or epidemiological testimony. Instead, they report facts known to geologists in the ordinary course of their work. For example, Dr. Krekeler's testimony that arsenic and nickel are "known human carcinogens" is grounded in

[24] *See, generally*, November 16, 2018 Expert Report of Arch "Chip" Carson, M.D., Ph.D. ("Carson Report") at 6–8, attached as **Exhibit 15**; May 28, 2024 Third Amended Expert Report of Daniel L. Clarke-Pearson, M.D. ("Clarke-Pearson Rep.") at 7–8, 13, attached as **Exhibit 16**; May 28, 2024 Expert Report of Michele L. Cote, Ph.D., M.P.H. ("Cote Report") at 11–12, 39, attached as **Exhibit 17**; November 15, 2018 Expert Report of Sarah E. Kane, M.D. ("Kane Report") at 5–6, 29, 36, attached as **Exhibit 18**; May 28, 2024 Second Amended Expert Report of Shawn Levy, Ph.D. ("Levy Report") at 18–19, attached as **Exhibit 19**; May 28, 2024 Third Amended Expert Report of Anne McTiernan, M.D., Ph.D. ("McTiernan Report") at 10, 85, 88, 101, attached as **Exhibit 20**; November 16, 2018 Expert Report of Patricia G. Moorman, MSPH, Ph.D. ("Moorman Report") at 35, attached as **Exhibit 21**; Plunkett Rep. at 24–25; May 27, 2024 Third Amended Expert Report of Jack Siemiatycki, MSc, Ph.D. ("Siemiatycki Report") at 27–28, 73–74, attached as **Exhibit 22**; November 16, 2018 Expert Report of Sonal Singh, M.D., MPH ("Singh Report") at 14, 16, 60, attached as **Exhibit 23**; November 16, 2018 Expert Report of Ellen Blair Smith, M.D. ("Smith Report") at 19, 21–22, attached as **Exhibit 24**; May 28, 2024 Third Amended Expert Report of Rebecca Smith-Bindman, M.D. ("Smith-Bindman Report") at 4, 11, 15, 37–38, 40, attached as **Exhibit 25**; May 28, 2024 Third Amended Expert Report of Judith Wolf, M.D. ("Wolf Report") at 13, 21, attached as **Exhibit 26**.

literature that has long recognized metals commonly found in talc as known or possible carcinogens.[25] It is standard practice for academic geologists and private sector analysts like himself to rely on such literature.[26] Dr. Krekeler's reliance on these materials is entirely appropriate and consistent with his academic and consulting work. Moreover, in his role as a Professor, Dr. Krekeler continuously updates his knowledge on the regulatory standards associated with geology and mineralogy in mining, including the heavy metals associated with talc ore designated as toxic by national and international regulatory bodies.[27] Defendants similarly ignore Dr. Cook's decades of experience as a professor and consultant which form his relevant expertise. He testified that he has experience in scoping studies by which he provides "a compilation of all information available on a particular topic."[28] Comparing scoping to his review here, Dr. Cook testified, "[I]t's exactly what . . . I did here . . . it's the same general intellectual exercise."[29]

Finally, Dr. Sage is qualified to opine on the regulatory practices and standards under which cosmetics manufacturers operate and whether Defendants complied with these standards in the development, manufacture, marketing, and sale of the

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[25] *See* Krekeler Report at 6–7, 33–34, attached as **Exhibit 11**.
[26] *See* January 25, 2019 Deposition of Mark Krekeler, Ph.D. ("Krekeler Dep.") at 324:9–11, 325:2–5, attached as **Exhibit 27**.
[27] *See* Krekeler Rep. at 6–7.
[28] January 30, 2019 Deposition of Robert Cook, Ph.D. ("Cook Dep.") at 462:4-462:16, attached as **Exhibit 28**.
[29] *Id*.

Talcum Powder Products.[30] In forming his opinions, Dr. Sage reviewed relevant laws and regulations, standards in the industry, peer-reviewed literature, publicly available information, and relevant corporate documents.[31] Based on this review, Dr. Sage noted that evidence revealed the Products "contain or may contain ingredients that pose health hazards to consumers" such as the heavy metals nickel, chromium, and cobalt and fragrance chemicals, and that the Defendants failed to inform consumers of the hazards and assure the safety of their products as required by federal regulation.[32]

2. The experts may properly rely on record evidence, published literature, and other experts' analyses to support their opinions.

Defendants argue that the PSC's experts improperly parrot the opinions of other experts concerning the presence and carcinogenic properties of heavy metals and fragrances because they did not perform independent analyses and lack the expertise to do so. Not so. The experts are not required to independently examine heavy metals and fragrances as a toxicologist, geologist, or mineralogist might, or to independently determine the contents of the Talcum Powder Products, as Defendants demand. Rather, Defendants' own authority confirms that experts are allowed to rely on a review of record evidence, published literature, and other

[30] November 15, 2023 Amended Expert Report of William Sage, M.D., J.D. ("Sage Report") at 2, attached as **Exhibit 29**.
[31] *Id*.
[32] *Id*. at 2, 5, 28.

experts' analyses in forming their opinions, like the PSC's experts did here. *See Torain v. City of Philadelphia*, CIVIL ACTION NO. 14-1643, 2023 WL 174952, at *5 (E.D. Pa. Jan. 12, 2023) (explaining that it is "well-established that experts may rely on record evidence and other experts' opinions in forming their own." (citing *Wisconsin v. Indivior Inc.*, No. 13-2445, 2020 WL 6887885, at *5 (E.D. Pa. Nov. 24, 2020)).

The PSC's experts reference credible evidence establishing the presence of chromium, nickel, and cobalt in the mines used to source the Talcum Powder Products for decades and in the finished Products, including Defendants' own internal documents and testing,[33] and identifying these metals as carcinogens and inflammatory agents.[34] Likewise, the experts properly reviewed and relied on Dr. Crowley's analysis to support their opinions that certain fragrance chemicals present in the Products further contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products as a whole.[35] *See Leese v. Lockheed Martin*

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[33] *See supra,* note 7. *See also* Cook Report, attached as **Exhibit 10** (thoroughly reciting test results); Krekeler Report, attached as **Exhibit 11** (same). *See also* Cote Report, **Exhibit 17**, at 11–12 (citing K.S. Almugren et al., *The presence of NORMs and toxic heavy metals in talcum baby powder*, 16 J. RADIATION RSCH. & APPLIED SCIS., no. 4, Aug. 2023, at 1).

[34] IARC (2012), attached as **Exhibits 4 and 5**; IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 86, Cobalt in Hard Metals and Cobalt Sulfate, Gallium Arsenide, Indium Phosphide and Vanadium Pentoxide (2006), attached as **Exhibit 6**.

[35] *See* November 12, 2018 Expert Report of Michael M. Crowley ("Crowley Rep.") at 64–65 (listing the evidence of the carcinogenicity, toxicity, genotoxicity,

Corp., 6 F. Supp. 3d 546, 553 (D.N.J. 2014) (noting that experts "may use a mix of objective data and subjective analysis from another expert" to create an admissible report (quoting *I.B.E.W. Local Union 380 Pension Fund v. Buck Consultants*, No. 03–4932, 2008 WL 2265269, at *3 (E.D. Pa. June 3, 2008)).

B. Plaintiffs' experts' opinions that the heavy metals present in J&J Talcum Powder Products play a contributing role in carcinogenesis are well-supported and reliable.

Defendants argue that the PSC's experts' opinions regarding heavy metals are unreliable because there are no scientific studies that link heavy metal exposure specifically to ovarian cancer and because the PSC's experts do not address dosage. These arguments are misplaced.

1. There is ample scientific evidence supporting the *biologically plausible mechanism* by which heavy metals operate to cause inflammation and carcinogenesis.

Contrary to Defendants' assertions, there is strong scientific support for the PSC's experts' opinions that the heavy metals contained in Defendants' Talcum Powder Products can contribute to ovarian cancer. Defendants attempt to distract from the legitimate scientific literature supporting the PSC's experts' opinions by making much of the lack of studies linking the heavy metals at issue to ovarian cancer *specifically*. But Defendants fail to consider that the PSC's experts opine that

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mutagenicity, and inflammatory properties of the chemicals that support his opinion), attached as **Exhibit 12**.

the Talcum Powder Products *as a whole* cause ovarian cancer, each heavy metal being just one constituent of a mixture. They do not opine that exposure to heavy metals themselves cause ovarian cancer. Thus, there is no need for studies that specifically link heavy metal exposure to ovarian cancer—that is not at issue in this case. Rather, the PSC's experts rely on extensive scientific evidence demonstrating the *biologically plausible mechanism* by which heavy metals operate to cause inflammation and carcinogenesis. This is more than sufficient to support the PSC's experts' opinions that the heavy metals within Talcum Powder Products can contribute to ovarian cancer.

And the proof is in the pudding. Indeed, both nickel and chromium VI have been classified by IARC as Group 1 carcinogens, meaning there is *sufficient evidence of carcinogenicity* in humans; moreover, cobalt has been classified by IARC as a Group 2B carcinogen, meaning it is *possibly carcinogenic* to humans.[36] When the IARC Working Group conducts a causation analysis, it considers the Bradford Hill criteria.[37] IARC considers all available data relevant to a classification of carcinogenicity, including epidemiological and experimental studies and mechanistic and other relevant data.[38] IARC also considers whether there is

[36] IARC, 2006 (**Exhibit 6**).
[37] IARC, 2012 Preamble at 21 (**Exhibit 3**).
[38] IARC, 2012 Preamble at 12–14 (**Exhibit 3**). IARC defines "carcinogenic" as "capable of increasing the incidence of malignant neoplasm, reducing their latency,

causation for multiple tumor types, temporality, effect, biological plausibility, changes at the cellular and molecular level, and the coherence of the overall data—the assessment *is not based on the availability of studies on a specific type of cancer*.[39]

The *sufficient evidence* of carcinogenicity standard needed for a Group 1 classification is met when, "a causal relationship has been established between exposure to the agent and human cancer."[40] Specific organs and tissues are identified where studies have specifically shown increased cancer risk, but the overall evaluation focuses on carcinogenicity where the agent acts through a "relevant mechanism"—findings applicable to all organs, including the ovaries.[41]

IARC published a monograph evaluating the carcinogenic risks posed to humans by arsenic, metals, fibres, and dusts in 2012,[42] and published a monograph evaluating the carcinogenic risks posed to humans by cobalt in hard metals and cobalt sulfate, gallium arsenide, indium phosphide and vanadium pentoxide in 2006.[43] As part of the expert reviews, the IARC Working Group evaluated relevant data, including genetic effects, oxidative stress, DNA damage and repair, and cell

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or increasing their severity or multiplicity." *Id.* The terms "neoplasm" and "tumo[u]r" are used interchangeably. *Id.*

[39] IARC, 2012 Preamble at 21–22 (**Exhibit 3**).

[40] *Id.* at 29.

[41] *Id.* at 30–32.

[42] IARC, 2012.

[43] IARC, 2006.

proliferation. The Agency for Toxic Substances and Disease Registry (ATSDR) has also described the carcinogenic mode of action (or mechanism) for nickel: "The available evidence suggests that, mechanistically, nickel carcinogenicity is probably the result of genetic factors and/or direct (e.g., conformational changes) or indirect (e.g., generation of oxygen radicals) epigenetic factors. Additionally, certain nickel compounds promote cell proliferation, which would convert repairable DNA lesions into nonrepairable mutations. Nickel is considered to be genotoxic…"[44]

And according to the ATSDR, chromium (VI), chromium (V), and chromium (IV) "have all been shown to be involved in Fenton-like oxidative cycling, generating oxygen radical species…"[45] "It is believed that the formation of these radicals, which leads to oxidative stress, may be responsible for many of the deleterious effects of chromium on cells…"[46] ATSDR describes the mechanism of action for cobalt to include the following: "Exposure to soluble cobalt increases indices of oxidative stress, including diminished levels of reduced glutathione, increased levels of oxidized glutathione, activation of the hexose monophosphate shunt, and free-radical-induced DNA damage…"[47] The National Toxicology

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[44] ATSDR, TOXICOLOGICAL PROFILE FOR NICKEL (Aug. 2005) at 155, relevant excerpts attached as **Exhibit 30**.
[45] ATSDR, TOXICOLOGICAL PROFILE FOR CHROMIUM (Sept. 2012) at 281, relevant excerpts attached as **Exhibit 31**.
[46] *Id*. at 282.
[47] ATSDR, TOXICOLOGICAL PROFILE FOR COBALT (Apr. 2004) at 154, relevant excerpts attached as **Exhibit 32**.

Program (NPT) has listed chromium (VI)[48] and nickel[49] as "known to be human carcinogens," while cobalt is listed as "reasonably anticipated to be human carcinogens."[50]

Defendants attempt to discount some of these agencies' findings because they reference certain "target" organs that are not ovaries. This argument is a red herring—the inclusion of certain target organs does not come at the exclusion of other organs. Indeed, in the previous *Daubert* ruling, Judge Wolfson found that "importantly, the IARC, in its 2012 Monograph explains that while it may identify certain carcinogens as having specific target organs or tissues where an increased risk of cancer has been shown, it further states that 'identification of a specific target organ or tissue *does not preclude* the possibility that the agent may cause cancer at other sites.'" *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 172 n. 39 (D.N.J. 2020) (citing Int'l Agency for Research on Cancer, 100C *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dusts*, at 29 (2012) (emphasis added)). Defendants themselves even admit that IARC's ultimate classifications are "not target organ oriented." Def. Memo. in Support at 17 n.51.

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[48] NATIONAL TOXICOLOGY PROGRAM, REPORT ON CARCINOGENS (15th ed. 2021), relevant excerpts regarding chromium, nickel, and cobalt attached as **Exhibit 33**.
[49] *Id.*
[50] *Id.*

Also, IARC and the ATSDR have both noted that the biological activities of all three metals—chromium (VI), cobalt, and nickel—result in inflammatory cell responses through oxidative stress, the formation of reactive oxygen species (ROS), and resultant DNA damage and genotoxic effects. These biologic activities are the *same biologically plausible modes of action* for Talcum Powder Products and ovarian cancer cited to by the PSC's experts.

Overall, Defendants' argument that there is insufficient evidence to support the PSC's experts' opinions about the heavy metals in *Baby Powder* and *Shower to Shower* and the biological mechanism by which they operate is without merit, and the opinions should not be excluded.[51]

2. Defendants have no factual basis for their argument that Chromium (VI) is not present in the Talcum Powder Products.

Grasping for straws, Defendants argue that the PSC's experts "ignore that chromium exists in different forms [i.e., valence states]" and that "there is no reason to think (let alone actual evidence) that chromium (VI) is present in talc, as opposed

[51] As *Daubert* specifically recognized, "cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" are the ordinary means to attack an opposing expert. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993). The United States Supreme Court has recognized that there is a range in which experts might reasonably differ on issues of science, and that such conflicting evidence should be admitted to aid the jury in deciding those issues. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 1953 (1999); *Ambrosini v. Labarraque*, 101 F.3d 129, 138-39 (D.C. Cir. 1996); *Globetti v. Sandoz Pharm. Corp.*, 111 F.Supp. 2d 1174, 1176 (N.D. Ala. 2000).

to chromium (III)." Def. Memo. in Support, at 20 n.54. This is not true. First, the difference between the valence states of chromium is pointed out in numerous PSC's experts' reports.[52] Further, Dr. Cook testified that he is aware of the distinction between chromium (III) and (IV), as they are the two forms most often associated with rock.[53] Dr. Plunkett explained that both chromium (III) and chromium (VI) have toxic properties, with varying levels of safe exposure.[54] And Dr. Smith-Bindman specifically distinguishes the chromium (VI) valence state when she describes its mechanism of carcinogenicity in her report.[55] Clearly, the PSC's experts are aware of the potential valence states of chromium.[56] However, their opinions are necessarily based on J&J's historical testing data from 1972 through 2003 that Defendants made available in this litigation. Defendants were aware of the different valence states of chromium but selected a testing procedure that failed to distinguish between chromium (III) and chromium (VI).[57] Having failed to conduct the

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[52] Krekeler Report at 7; *see also* Smith-Bindman Report at 15, attached as **Exhibit 25**.

[53] *See* Cook Dep. at 402:15–404:10, attached as **Exhibit 28**.

[54] Plunkett Dep. at 411:11–16 ("Both chrome III and chrome VI have toxic properties, specifically irritant properties as well, but they may be looked at separately, for example, in the regulatory context when you set safe levels of exposure.")

[55] Smith-Bindman Report at 15.

[56] All of the PSC's experts who refer to the carcinogenicity of chromium cite to IARC, 2012, which clearly and specifically discusses the carcinogenicity of chromium (VI) as distinguished from chromium (III).

[57] Cook Dep. at 403:21–404:4 ("…the technique used by Johnson & Johnson would not distinguish between the two, and their – their specs don't try to distinguish

necessary testing, Defendants cannot now ask the court to assume that all chromium found was chromium (III).

While the PSC's experts did not engage in their own testing of talc ore or powder samples for heavy metals, they reviewed and reported on J&J's and Imerys Talc America, Inc.'s testing and the testing performed by third parties on their behalf. Additionally, J&J knew that chromium (VI) exists in talc mines—that knowledge is reflected in J&J's internal documents reviewed by the PSC's experts.[58] Plaintiffs know of only one instance where J&J specifically tested for chromium (VI) in "Talc Powder" samples, and in that analysis, chromium (VI) was present at an average of 75 ppb.[59]

The PSC's experts also have evidence that the chromium found in the Talcum Powder Products is likely to be chromium (VI). Chromium (VI) is most commonly derived from industrial processes but is also produced naturally through the oxidation of chromium (III) by manganese minerals,[60] and chromium (VI) is soluble

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between the two"); *see also* Plunkett Dep. at 411:2–7 ("Ionic chromium as detected within the documents that – where the measurement were made of the actual talc samples that were processed and made into baby powder, which did not necessarily distinguish between chrome III and chrome VI.").

[58] **Exhibit 34**, JNJ 000131754 at 755 ("In mine the Chromium exists mainly as Hexavalent chromium and Chromium trioxide. Hexavalent chromium is the most toxic compound among all of chromium oxide…").

[59] **Exhibit 35**, JNJ 000378046, document was reviewed by Plaintiffs' expert Dr. Cook.

[60] C. Oze et al., *Genesis of hexavalent chromium from natural sources in soil and groundwater*, 104 PNAS 6544 (2007), attached as **Exhibit 36**.

in water.[61] Chromium is found at concentrated levels in the ultramafic rock of the Earth's crust,[62] the very rock found in Vermont that is altered into serpentinites and talc. Heavy metals are frequently contained in chlorite species, which are consistently reported as abundantly present in mine core logs[63] from the Argonaut talc mine,[64] as well as in other internal reports and studies.[65] High levels of heavy metals including chromium, cobalt, and nickel were consistently found in the talc ore from Vermont talc mines used to source J&J talc between 1972 and 2003.[66] More importantly, high levels of the same heavy metals were likewise found *in the finished Grade 66 product* from the Vermont mines used in the J&J Talcum Powder Products.[67] The PSC's experts Drs. Cook and Krekeler document the existence of heavy metals in the finished products in their reports.[68]

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[61] IARC, 2012 (**Exhibit 5**).
[62] Oze, *supra* note 60.
[63] "Core logs" refers to the recorded lithology (rock types) and mineralogy of sections of cylindrical core drilled from rock or a mineral deposit.
[64] *See, e.g.*, **Exhibit 37**, IMERYS 469483 at 484.
[65] **Exhibit 38**, IMERYS 441340 at 364 (average chlorite content is 4.01% according to a 2008 ore reserve study).
[66] **Exhibit 39**, JNJ 000246437 (shows high levels of chromium, cobalt, and nickel in a 1990 sample from the Hamm mine in Vermont).
[67] **Exhibit 7**, JNJ 000237076 (showing two Grade 66 samples from the Hammondsville mine in Vermont in 1991 contained high levels of chromium, cobalt and nickel); **Exhibit 8**, IMERYS 342524 (showing high levels of chromium, cobalt, and nickel in a 1997 annual composite sample of Grade 66 talc as measured using two different testing methods).
[68] *See* Cook Report at 28–34, attached as **Exhibit 10**; Krekeler Report at 31–33, attached as **Exhibit 11**.

The chromium levels measured well over *200 ppm* in many samples of both the talc ore and talcum powder product when J&J's specification limit for chromium in Talcum Powder Products was only *0.5 ppm*.[69] Additionally, J&J's and Imerys Talc America, Inc's internal documents indicate they were aware chromium (VI) was present both in the talc mines[70] *and in the finished products*—this explains J&J's single test to determine the ratio of chromium valence states.[71]

3. Defendants' arguments about dosage are misplaced.

a. A qualitative analysis is appropriate for assessing the safety of mixtures like J&J's Baby Powder and Shower-to-Shower.

As stated above, J&J's *Baby Powder* and *Shower to Shower* are mixtures composed of numerous constituents, including platy talc, fibrous talc, asbestos, heavy metals (cobalt, nickel and chromium), and fragrance chemicals. Asbestos, and the metals nickel and chromium are known human carcinogens. Fibrous and platy talc are considered by IARC to be probable carcinogens.[72] Mixtures are defined "as any combination of two or more chemical substances regardless of source or of spatial or temporal proximity."[73] The EPA's Supplementary Guidance for

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[69] *See* June 28–29, 2018 Deposition of Donald Hicks ("Hicks Dep.") at 79:1–3, attached as **Exhibit 40**.
[70] **Exhibit 34**, JNJ 000131754.
[71] **Exhibit 35**, JNJ 000378046.
[72] IARC, 2024 (**Exhibit 1**).
[73] U.S. EPA, SUPPLEMENTARY GUIDANCE FOR CONDUCTING HEALTH RISK ASSESSMENT OF CHEMICAL MIXTURES (2000), at Appendix A, A-1, https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533 (last accessed August 14, 2023), relevant excerpts attached as **Exhibit 41**.

Conducting Health Risk Assessment of Chemical Mixtures sets forth the human risk assessment process to use on mixtures like the Talcum Powder Products that contain carcinogenic components.[74]

The EPA specifically recognizes that "most frequently, *not all components of the mixture are known*, exposure data are uncertain, and toxicologic data on the known components of the mixture are limited."[75] Where this occurs, as in the case with J&J's Talcum Powder Products, the lack of quantitative data may lead the risk assessor to decide that *a qualitative analysis should be performed*.[76] This generally occurs in cases where data quality is poor, adequate quantitative data is not available, data on a similar mixture cannot be classified as sufficiently similar to the mixture of concern, exposures cannot be characterized with confidence, or where method-specific assumptions about the toxicologic action of the mixture or its components cannot be met.

A qualitative assessment is appropriate for characterizing the potential human health impacts from exposure to mixtures in these situations.[77] In the case of mixtures containing known carcinogens, the default approach is to assume that there are additive effects among the constituents, or "potential interactions among the

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[74] *Id.*
[75] *Id.* at Appendix A, A-1 (emphasis added).
[76] *Id.* at 11.
[77] *Id.*

components."[78] This approach is appropriate for assessing the J&J's Talcum Powder Products—which again, are mixtures containing known carcinogens—and is fully supported by the PSC's experts and the scientific literature.

b. Dose response, and thresholds of exposure are not required as part of a qualitative risk assessment and are not necessary to support the PSC's experts' opinions because there are established "biologically plausible" mechanisms explaining how the heavy metals promote cancer.

Defendants incorrectly assert that dose-response and thresholds of exposure are *required* to support the PSC's experts' opinions about the heavy metals in the products. But as Judge Wolfson previously acknowledged, "while precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert's opinion on causation." *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d at 179 (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 264 (4th Cir. 1999)); *see also Ferguson v. Riverside Sch. Dist. No. 416,* 2002 WL 34355958, at *6 (E.D. Wash. Feb. 6, 2002) ("The Court determines that the lack of a model for determining causation

[78] *Id.* at A-7.

based on a 'dose-response' relationship does not undermine the reliability of [the expert's] testimony.").

Moreover, these factors are not required under the qualitative risk assessment process approved by the EPA and described above. Nor does the Bradford Hill analysis require a dose assessment of the individual constituents in mixed products like the J&J's Talcum Powder Products. Rather, the Bradford Hill dose response analysis for the genital application of talcum powder and ovarian cancer evaluates the duration and frequency of exposure of the entire product with reference to the epidemiological data as a whole.[79] The PSC's allegation is that the J&J's Talcum Powder Products as a whole—that is, *the mixture of all constituent parts*—cause ovarian cancer, not any single constituent part acting alone.

And, dose-response and threshold determinations are distinct and separate from the Bradford Hill *biologic plausibility mode of action* that the PSC's experts' opinions are based on. The term "mode of action" is defined by the USEPA as "a series of key events and processes starting with interaction of an agent with a cell and proceeding through operational and anatomical changes causing disease

[79] *See generally* PSC Gen. Causation Opp.; *In re Acetaminophen - ASD-ADHD Prod. Liab. Litig.*, 22MD3043, 2023 WL 8711617, at *19 (S.D.N.Y. Dec. 18, 2023) ("No single Bradford Hill factor is required to infer causation; the criteria are neither an exhaustive nor a necessary list." (internal quotations omitted)); *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.,* No. 2007–MD–1871, 2011 WL 13576, at *14 (E.D. Pa. Jan. 4, 2011) (determining expert's Bradford Hill analysis was reliable despite the expert being unable to assess a dose response).

formation."[80] This definition is also consistent with the Bradford Hill aspect of plausibility.

Biologic plausibility (one of the Bradford Hill considerations for causal inference) "depends upon existing knowledge about the mechanisms [mode of action] by which the disease develops [and] on the extent of scientific knowledge about the cellular and subcellular mechanisms through which the disease process works."[81] "What is biologically plausible depends upon the biological knowledge of the day."[82] Given the complexity of cancer biology, a biologically plausible mechanism should not have to establish "all levels of scientific explanation" for "each step" in the cancer process as this is "too stringent" and "overdemanding."[83] What is required, however, is that the proposed "mode of action and the events that are part of it be based on current understanding of the biology of cancer to be accepted."[84] The use of an adverse pathway model is also a recognized approach to determining a biological plausible mechanism. In this model, the chemical toxicities

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[80] USEPA, 2000 (**Exhibit 41**) at 10.
[81] REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 604–05.
[82] A.B. Hill, *The Environment and Disease: Association or Causation?*, 58 PROCS. ROYAL SOC'Y MED. 295, 296–300 (1965), attached as **Exhibit 42**.
[83] D.L. Weed & S.D. Hursting, *Biologic Plausibility in Causal Inference: Current Method and Practice*, 147 AM. J. EPIDEMIOLOGY 415, 416–425 (1998), attached as **Exhibit 43**.
[84] R. Golden et al., *Formaldehyde as a potential human leukemogen: an assessment of biological plausibility*, 36 CRITICAL REVS. TOXICOLOGY 135, 136–153 (2006), attached as **Exhibit 44**.

and properties of a chemical [toxicant] is first considered and characterized then followed along a toxicity pathway that investigates the toxicants molecular (DNA) interaction and impact, cellular responses, and organ responses followed by an investigation of population responses (epidemiology).[85]

This is precisely the model the PSC's experts appropriately used to assess the role of the constituent parts of the J&J Talcum Powder Products, and their respective testimony is consistent regarding the heavy metals' biologically plausible mechanism—inflammation:[86]

- **Dr. Carson** testified that a dose response assessment is not necessary as part of a qualitative analysis: "A qualitative risk assessment does not necessarily require a dose-response in order to reach valid conclusions."[87]
- **Dr. Carson** also testified that the heavy metals contribute to the inflammatory process and carcinogenicity: " . . . my opinion is that any [amount of nickel, chromium, cobalt] within the microenvironment of the inflammatory process that is occurring due to talc sequestration is contributing to the carcinogenic potential."[88]
- **Dr. Levy** testified that chronic inflammation is a well-established biologic mechanism of cancer, including ovarian cancer, both in the initiation and the progression of the cancer.[89] He described the role of inflammation in cancer

[85] J. Dailey et al., *Evaluating biological plausibility in supporting evidence for action through systematic reviews in public health*, 165 PUB. HEALTH, Oct. 2018, at 48–57, attached as **Exhibit 45**.
[86] Constituents of Talcum Powder Products with a contributory role in ovarian cancer risk include platy talc, heavy metals (chromium, nickel and cobalt), asbestos and fibrous talc.
[87] *See* January 19, 2019 Deposition of Arch I. "Chip" Carson, M.D., Ph.D. ("Carson Dep.") at 173:8–10, attached as **Exhibit 46**.
[88] *Id.* at 171:16–21.
[89] *See* January 11, 2019 Deposition of Shawn Levy, Ph.D. ("Levy Dep.") at 116:17–24 and 117:1–2, attached as **Exhibit 47**.

as a "fundamentally accepted aspect of cancer biology"[90] and not a "hypothetical."[91] Dr. Levy further described the established carcinogenic mechanisms of chromium and nickel to include "DNA damage, mutation, genomic instability, and cell transformations."[92] He stated that cobalt was "shown to increase production of reactive oxygen species (ROS) and other inflammatory and proliferative changes."[93] The presence of the known carcinogens nickel and chromium, as well cobalt, which is "reasonably anticipated" to be carcinogenic, in talcum product supports his opinion that the Talcum Powder Products cause inflammation.[94]

- **Dr. Plunkett** testified that, "Inflammation is a well- studied mechanism of carcinogenesis."[95] In outlining the role of inflammation in cancer, Dr. Plunkett explained: "there are several basic facts about inflammation and cancer that include the following: (1) chronic inflammation increases cancer risk; (2) subclinical, often undetectable inflammation may be as important in increasing cancer risk; (3) various types of immune and inflammatory cells are frequently present within tumors; (4) immune cells affect malignant cells through production of cytokines, chemokines, growth factors, prostaglandins, and reactive oxygen and nitrogen species; (5) inflammation impacts every single step of tumorigenesis, from initiation through tumor promotion, all the way to metastatic progression; (6) in developing tumors anti- tumorigenic and pro-tumorigenic immune and inflammatory mechanisms coexist, but if the tumor is not rejected, the pro-tumorigenic effect dominates; (7) signaling pathways that mediate the pro-tumorigenic effects of inflammation are often subject to a feed-forward loop; and (8) certain immune and inflammatory components may be dispensable during one stage of tumorigenesis but absolutely critical in another stage."[96]
- For the Talcum Powder Products and their heavy metal constituents (cobalt, chromium, and nickel), **Dr. Plunkett** concluded, ". . . the scientific literature on the biological effects of talc, as well as asbestos and other constituents routinely found in talc . . . provide sufficient evidence to show that these chemicals produce cellular changes that have been linked to carcinogenesis

[90] *Id.* at 263:2–17.
[91] *Id.* at 294:1–14.
[92] *See* Levy Report at 19, attached as **Exhibit 19**.
[93] *Id.* at 16.
[94] *Id.*
[95] Plunkett Report at 49, attached as **Exhibit 2**.
[96] *Id.* at 49–50.

and that the biological mechanism for carcinogenesis (ovarian and/or lung) following exposure to talcum powder products likely involves induction of a chronic inflammatory response. A review of the IARC monographs for talcum powder product constituents, such as asbestiform talc and non-asbestiform talc, nickel, cobalt, and chromium, reveals similarities in the biological effects that are discussed as underlying the carcinogenic potential of the individual compounds."[97]

- **Dr. Plunkett** further explained that, "the available data relating to mechanism of carcinogenicity of talcum powder products, where the body powders are a mixture of compounds with carcinogenic hazard, indicate that the various compounds in talcum powder products would be expected to produce at least an additive effect on the risk of cancer based on their ability to induce similar biological responses that underly carcinogenesis."[98] Dr. Plunkett also explained that the three heavy metals (cobalt, chromium, and nickel) have a similar biological plausibility mechanism—they cause irritation and inflammation.[99]

- **Dr. Plunkett** also discussed the complex mixture of J&J Talcum Powder Products, indicating that "when you have a complex mixture that has added to it things like asbestos and heavy metals, because I talk about the additivity issue that can come to play. So that -- in other words, [there is an] increased risk when you have a complex mixture with additional components that all share the same toxic properties as far as target organs or types of effects or mechanisms that are triggered in the body."[100]

- **Dr. Carson** similarly recognized that "talcum powder may contain varying amounts of chromium, cobalt and nickel, metal ions that are recognized as cancer causing."[101] Dr. Carson reported, "these ions leach out of the talcum powder slowly over time, resulting in continuous, low-level exposure of the surrounding tissues to carcinogenic metals"[102] and that "the presence of carcinogenic metals such as, chromium, cobalt and nickel, and toxic fragrance components in commercial Talcum Powder Products, adds to their

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[97] *Id.* at 50–51.
[98] *Id.* at 51.
[99] *See* Plunkett Dep. at 268:7–13, attached as **Exhibit 14**.
[100] *Id.* at 146:11–21.
[101] *See* Carson Report at 5, attached as **Exhibit 15**.
[102] *Id.* at 5.

> carcinogenic potency."[103] In describing the mode of action of these metals, Dr. Carson reported that they are "liberated in bodily fluids and tissues and are free to exert their carcinogenic effects"[104] and "once reaching the target tissues, talcum powder and its constituents initiate carcinogenesis via multiple means, including, inflammation with chemotaxis of inflammatory cells, liberation of cytokines, and reactive oxygen species, inactivation of TP53 genetic modulator, inhibition of DNA repair, and long-term promotion of genetic mutations via continuous inflammation and cellular growth stimulation."[105]

As discussed in great detail above, the PSC's experts did not need to conduct a dose response assessment of the individual constituents because they evaluated the dose of Talcum Powder Products as a whole—that is, *as a mixture* of the constituents. It is the *entire* product, including its constituents, that trigger carcinogenesis.

C. Dr. Michael Crowley's opinions regarding the fragrance chemicals in J&J's Talcum Powder Products are well-supported and reliable.

1. Dr. Crowley offers reliable scientific testimony and is well qualified under Rule 702.

The recent amendments to Rule 702 did not change the rule's procedures, standards, or substantive requirements.[106] Dr. Crowley's testimony meets the

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[103] *Id.* at 7.
[104] *Id.* at 8.
[105] *Id.* at 10.
[106] *See Johnson v. Comodo Grp., Inc.*, No. 2:16-04469, 2024 WL 2933195, at *4 n.6 (D.N.J. June 10, 2024) (unpublished) ("The amendment does not substantively alter Rule 702 but rather 'clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000—requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard.'") (quoting Adv. Com. Notes to Rule 702 (2023); *Walden v. Bank of N.Y. Mellon Corp.*, No. 2:20-CV-01972, 2024 WL 343087, at *2 n.3 (W.D. Pa.

reliability threshold of Rule 702, before and after the amendments, in that it is "based on the methods and procedures of science, not on subjective belief and unsupported speculation."[107] Indeed, Dr. Crowley's opinion is based on his review as a chemist with superior knowledge, skill and experience, of *data accepted within the scientific community* related to the fragrance chemicals used in J&J Talcum Powder Products. *See Daubert,* 509 U.S. at 593-94, 113 S. Ct. 2786. His methodology is reliable and admissible: "[t]he opinion of a qualified expert 'is admissible so long as the *process or technique* [as opposed to the conclusion] the expert used in formulating the opinion is reliable.'" *Knight v. Avco Corp.*, No. 4:21-CV-00702, 2024 WL 3746269 (M.D. Pa. Aug. 9, 2024) (emphasis in original) (citing *In re TMI Litigation*, 193 F.3d 613, 664 (3d Cir. 1999) (citing *In re Paoli Railroad Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994)) (emphasis in original). Both Dr. Crowley's process and technique are reliable and meet Rule 702's admissibility standards.

Defendants mischaracterize Dr. Crowley's opinion as one of medical causation instead of one based in his field of chemistry: he does not opine as to whether J&J's fragrance chemicals cause ovarian cancer but instead offers his opinion as to the chemical properties of J&J's fragrance chemicals, whether they

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Jan. 30, 2024) (*Daubert* legal standard not substantively changed by 2023 amendment).

[107] *See UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 833–34 (3d Cir. 2020) (quoting *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 80–81 (3d Cir. 2017).

met regulatory standards, and whether they can contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the Talcum Powder Products as a whole.

To do this, Dr. Crowley employed his skills as a chemist and his experience working in the field. He earned his B.S. in chemistry from the University of Missouri-St. Louis, his M.A. in organic chemistry from Washington University in St. Louis, and his Ph.D. in molecular pharmaceutics from the University of Texas.[108] He has served as a consultant to more than fifty companies, primarily in the pharmaceutical industry, in the areas of proof of concept, formulation and product development, drug delivery and clinical development, including generation of FDA regulatory submissions.[109] Previously, he worked for a startup pharmaceutical company that developed novel drug products to treat infectious disease, as well as a contract research organization that provided formulation and drug product development services.[110] He has vast experience in chemistry and chemical formulation, including studying, reviewing, and assessing the safety of all types of chemicals, including several that are in the Talcum Powder Products.

Over the years, Dr. Crowley has developed many pharmaceutical

[108] Crowley Report at 14; *see also* January 4, 2019 Deposition of Michael Crowley, Ph. D. ("Crowley Dep.") at 341:20–23, attached as **Exhibit 48**.
[109] Crowley Report at 14.
[110] *Id.* at 14.

formulations, nutritional supplements, and food products, including developing over fifty formulations that have been tested in human clinical studies.[111] He has authored or co-authored over fifteen clinical study protocols and over thirty published articles and abstracts and four book chapters relating to his work.[112] He is an inventor of five United States patents and a number of foreign patents and pending applications.[113] He has served as a reviewer for many peer-reviewed journals. [114]

Perhaps most relevant to his task in this litigation is Dr. Crowley's experience creating chemical formulas for various pharmaceutical and cosmetic products. Examples include: formulating a fragrance for use in a prenatal vitamin;[115] formulating a cosmetic facial mask;[116] and formulating pharmaceutical products for vaginal use, including Crinone and vaginosis and fungal vaginosis products.[117] As part of Dr. Crowley's work in the field of chemical formulation, he regularly reviews the safety profiles of chemicals to determine whether they are safe to use in his clients' products. This is the same methodology he exercised in this litigation, and precisely the type of methodology required under Rule 702.

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[111] Crowley Report at 14; Crowley Dep. at 342:1–11
[112] Crowley Report at 14–15.
[113] *Id.* at 15.
[114] *Id.*
[115] Crowley Dep. at 52:14– 23.
[116] *Id.* at 52:3–5.
[117] *Id.* at 205:1–9.

2. Dr. Crowley employed the same systematic methodology to review the fragrance chemicals in J&J's Talcum Powder Products that he regularly uses in his own work with consumer products.

Dr. Crowley described in detail at his deposition how the methodology he employed in this case is the same process that he regularly uses as a chemist and chemical formulator for consumer products. He reviewed the totality of available safety data for each fragrance chemical used in the Talcum Powder Products: "I tried to examine the totality of the evidence for each and every chemical and collate that . . . in a meaningful way to examine their properties and to answer the questions that were posed to me.[118]

First, Dr. Crowley took the list of fragrance chemicals used in J&J *Baby Powder* and *Shower-to-Shower* and tried to identify a CAS (Chemical Abstracts Service) number for each so he could cross-reference it with various databases and gather physical and chemical properties, as well as safety profiles, *in vitro* and/or *in vivo* studies, and any published or known pharmacological properties about the chemicals.[119] He reviewed the IFRA (International Fragrance Association), CIR (Cosmetic Ingredient Review), and FDA (Food and Drug Administration) websites, particularly the FDA's Inactive Ingredient Database.[120] He reviewed journals,

[118] Crowley Dep. at 111:7–15.
[119] *Id.* at 109:13–19.
[120] *Id.* at 109:20–23.

including Food and Chemical Toxicology, to see what studies were available, as well as the EFSA (European Food Safety Authority) website, and the RTECS (Registry of Toxic Effects of Chemical Substances) website, all with the goal of gathering as much pertinent information about the chemicals as possible.[121] He classified the chemicals according to whether they are established irritants, sensitizers, or allergens.[122] He then compiled all of his relevant findings into detailed tables and appendices in his report.

Dr. Crowley explained that this is exactly what "a standard formulator" like himself does to determine whether chemicals are safe to use in consumer products.[123]

Accordingly, Dr. Crowley looked to the available regulatory information, studies, and technical literature on these issues and opined as to whether someone in the chemical formulation industry like himself would have concerns about using those chemicals in consumer products, either because of regulatory issues or because of their potential to contribute inflammatory, toxic, and/or potentially carcinogenic properties to the products.[124]

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[121] *Id.* at 110:1–22.
[122] *Id.* at 110:8–13.
[123] *Id.* at 112:23–113:4; 186:22–187:12.
[124] To the extent J&J criticizes Dr. Crowley for not performing his own "risk analysis" of each chemical, he explained that he did not need to do so because that work has "already been done and published in the literature." Crowley Dep. at 132:20–133:2. *Daubert* requires the proponent of the scientific evidence to show that the expert's conclusion has been arrived at "in a scientifically sound and methodologically reliable fashion," not that the expert's opinion or methodology is

3. Dr. Crowley has ample "good grounds" to support his opinions about the fragrance chemicals in J&J's Talcum Powder Products and their link to ovarian cancer.

Defendants argue that Dr. Crowley's review of the chemicals was "haphazard" and that his opinions "lack good grounds." However, a closer analysis reveals that this opinion stems from Defendants' misunderstanding of the chemicals used in J&J's own products and the way those chemicals are classified by regulatory bodies. Moreover, Dr. Crowley provides, both in his report and in his deposition, evidence of association between ovarian cancer – *specifically* – and exposure to the fragrance chemicals in the Talcum Powder Products.

- **Styrene (Benzene, ethenyl-):** At Dr. Crowley's deposition, counsel for J&J incorrectly stated that styrene has an IARC Group 2B classification, meaning that it is "possibly" carcinogenic to humans."[125] Remarkably, J&J *yet again* incorrectly categorizes styrene in its brief, this time claiming that it has an IARC Group 3 classification.[126] Dr. Crowley corrected J&J's first misclassification error at his deposition—styrene is classified by IARC in the 2A group, meaning that it is "*probably* carcinogenic to humans."[127] As Dr. Crowley explained:

  "IARC 2A is probably carcinogenic to humans. It means limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in animal studies or inadequate evidence of carcinogenicity in humans and

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beyond reproach. *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998); *In re TMI Litig.*, 193 F.3d 613, 665 (3rd Cir. 1999) (explaining that plaintiffs "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable" (citation omitted)).

[125] Crowley Dep. at 244:13–14.

[126] Def. Memo. in Support at 34.

[127] **Exhibit 13**, IARC 2A classification for styrene.

sufficient evidence of carcinogenicity in animals, and strong evidence that the carcinogen is meted by a mechanism that does operate in humans."[128]

Dr. Crowley also testified that the National Toxicology Program has determined that styrene is reasonably anticipated to be a human carcinogen.[129] Dr. Crowley provides numerous sources for his conclusions regarding styrene in his report, including, but not limited to: styrene has been implicated as a reproductive toxicant, neurotoxicant, or carcinogen in vivo or in vitro; the *FDA has banned styrene's use as a synthetic flavoring substance; styrene has been observed to cross the placenta in studies;* styrene's metabolite styrene 7,8- oxide is genotoxic; and styrene has been linked to cytogenic, DNA damage, DNA inhibition, sister chromatid exchange, and unscheduled DNA synthesis in multiple in vitro models.[130]

Indeed, the information provided by J&J regarding compositional changes to its Talcum Powder Products indicates that J&J *decided to remove styrene* from the products around 2014.[131] Accordingly, there is more than ample basis for Dr. Crowley to reach his conclusion that the use of styrene in consumer cosmetic products like J&J *Baby Powder* and *Shower to Shower* poses both regulatory concerns and can contribute to the inflammatory properties, toxicity, and/or potential carcinogenicity of the Talcum Powder Products as a whole.

- **Coumarin, Eugenol, and D-limonene**: While Defendants are correct that coumarin, eugenol, and D-limonene (unlike styrene) have IARC Group 3 classifications, Defendants present an incomplete definition of what that classification means and ignores the other data Dr. Crowley relies on to reach his conclusions about the chemicals' ability to contribute to the inflammatory, toxic, and/or carcinogenic properties of the Talcum Powder Products.

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[128] Crowley Dep. at 358:5–18.
[129] Crowley Report at 22–23 (emphasis added); *see also* Crowley Dep. at 255:7–13 ("Styrene 7,8-oxide has been implicated and found to be carcinogenic and genotoxic in virtually every study that has ever been done with it. Metabolism of styrene to those metabolites have also been demonstrated both in humans and in animals to be carcinogenic.").
[130] *Id.* at 359:13–18.
[131] Crowley Dep. at 142:10–14; Crowley Report at 13, n.1.

It is incomplete to describe IARC Group 3 chemicals as "not classifiable" as to carcinogenicity because there is "inadequate evidence that the substance causes cancer in humans."[132] Defendants offered the same half-explanation at Dr. Crowley's deposition, and he supplied the remaining pertinent information at that time. In Dr. Crowley's own words: "No. That's only half of it. The other part of that is evidence of carcinogenicity is inadequate in humans *but sufficient in experimental animals*, but strong evidence that the mechanism of carcinogenicity in experimental animals *may not operate in humans*, or agents that don't fall into any other group."[133] In other words—there is evidence of carcinogenicity in animal studies, but it is *not yet fully established* whether the carcinogenic mechanism operates similarly in humans.

Accordingly, Dr. Crowley is not mistaken in saying that coumarin, eugenol, and d-limonene are "potential carcinogens" because there is "sufficient" evidence of those chemicals' carcinogenicity in animals, while human carcinogenicity is simply not yet established. *Coumarin has been banned in foods since 1954, it is not listed by the CIR, a 2018 study links it to the development of liver tumors in rats and mice* and Clara cell toxicity and lung tumors in mice, it causes fetotoxicity in rats, and it results in sister chromatid exchange in hamster ovary cells.[134]

Eugenol has been shown to cause sister chromatid exchange and chromosome aberration in hamster ovary cells.[135] Likewise, *D-limonene causes reproductive effects in mice and rats following oral administration and cytotoxicity in hamster ovary cells*.[136] All of this information taken together is sufficient to support Dr. Crowley's opinion that coumarin, eugenol, and d-limonene can contribute to the inflammatory properties, toxicity, and/or carcinogenicity of J&J *Baby Powder* and *Shower to Shower*.

- **Benzophenone:** Defendants challenge Dr. Crowley's conclusions about benzophenone, which was recently removed from use in foods by the FDA, because the 2006 NTP study he cited "did not conclude that benzophenone can cause ovarian cancer."[137] Benzophenone is an IARC Group 2B chemical,

[132] Def. Memo. in Support, at 33.
[133] Crowley Dep. at 239:1–8 (emphasis added).
[134] Crowley Report at 23–24.
[135] *Id.* at 24.
[136] *Id.* at 21.
[137] Def. Memo. in Support, at 34.

meaning it is possibly carcinogenic to humans.[138] It is no longer listed in the CFR for food use and it has no IFRA standard.[139] It is associated with an increased risk of "hepatoblastoma in male mice, histiocytic sarcoma in female mice, increased incidence of mononuclear cell leukemia in male and female rats[,] [r]enal tube adenoma in male rats, histiocytic sarcoma in female rats, and tumors in the kidney."[140] And importantly, the 2006 NTP study that J&J references *does link benzophenone to ovarian abnormalities*. Dr. Crowley read from the NTP report in pertinent part at his deposition:

"So this is from the NTP report, and I'm going to read it. Histiocytic sarcoma in females. There was a positive trend in the incidence of histiocytic sarcomas, all organs . . . In the current two-year study, only females were affected, and the liver and lung were involved in all affected females. The histiocytic sarcomas were highly invasive in all three 1,250 PPM mice. *Multiple organs throughout the body had neoplastic histiocytic legions; ovaries*, *uterus*, spleen, adrenal gland, kidney, urinary bladder, and multiple lymph nodes were affected in all three animals."[141]

As Dr. Crowley stated, "frankly, [the] NTP is extraordinarily thorough."[142] The NTP study showed that male rats receiving benzophenone had severe kidney nephropathy, kidney tumors, and leukemia.[143] Female rats had higher rates of leukemia, liver tumors, increased severities of kidney nephrology, metaplasia, epithelia of the nose and hyperplasia of the spleen.[144] The NTP program also concluded that benzophenone caused cancer – kidney cancer in male rats, liver tumors in male mice, and histiocytic sarcomas in female mice."[145] Additionally, "in vivo estrogenic activity of benzophenone was confirmed in the uterotrophic assay" by IARC in 2013.[146] This abundance of data more than supports Dr. Crowley's opinions regarding benzophenone and its ability to contribute to the inflammatory properties, toxicity, and/or carcinogenicity of J&J's Talcum Powder Products.

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[138] Crowley Dep. at 276:17–21.
[139] Crowley Report at 47.
[140] Crowley Dep. at 277:10–16.
[141] *Id.* at 279:12–280:13 (emphasis added).
[142] *Id.* at 277:23–24.
[143] *Id.* at 278:1–4.
[144] *Id.* at 278:4–8.
[145] *Id.* at 277:21–278:16.
[146] Crowley Report at 48.

- **P-cresol:** Defendants challenge to Dr. Crowley's opinions regarding p-cresol rests on a single review from the Agency for Toxic Substances and Disease Registry, which concluded that there is inadequate information to assess p-cresol's carcinogenic potential.[147] However, the EPA has categorized p-cresol as "possibly carcinogenic" from 1990 to the present day.[148] Studies show that p-cresol is cytogenetic in hamster ovary cells and causes DNA damage in human lymphocytes.[149] In 2006, the CIR Expert Panel found that "in the p-cresol assay . . . there were significant increases in chromosomal aberrations at all concentrations tested," and "p-cresol was considered positive for inducing chromosomal aberrations in CHO cells under both activation and nonactivation conditions."[150] Further, the **CIR does not permit p-cresol for use in cosmetics that are applied to mucous membranes**.[151] Older studies demonstrated that women exposed in the workplace to varnishes containing mixed cresols had increased gynecological problems such as menstrual disorders and hormonal disturbances, and an increased frequency of perinatal mortality and abnormal development of newborn infants.[152] Here again, there is sufficient data to support Dr. Crowley's opinion regarding p-cresol's contribution to the inflammatory properties, toxicity, and/or carcinogenicity of J&J's Talcum Powder Products, and a single review from the Agency for Toxic Substances and Disease Registry does not discredit all other evidence.

- **Musk ketone:** Defendants discuss musk ketone in their brief, but don't explain what, if anything, was inaccurate or "haphazard" about Dr. Crowley's review of the chemical. Defendants are correct—musk ketone is classified as a Category 3 carcinogen by SCHER (Scientific Committee on Health and Environmental Risks), and is suspected of being a carcinogen.[153]

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[147] Def. Memo. in Support, at 35.

[148] *See* U.S. EPA, HAZARD SUMMARY: CRESOL/CRESYLIC ACID (2000), https://www.epa.gov/sites/default/files/2016-09/documents/cresol-cresylic-acid.pdf (last accessed August 16, 2024); at 1 ("Several animal studies suggest that o-cresol, m-cresol, and p-cresol may act as tumor promotors. EPA has classified o-cresol, m-cresol, and p-cresol as Group C, possible human carcinogens.").

[149] Crowley Report at 25 (citing RTECS).

[150] *Id.* at 25.

[151] *Id.* (citing Cosmetic Ingredient Review Expert Panel, 2006) (emphasis added).

[152] *Id.* at 26 (citing Syrowadko & Malysheva, 1977).

[153] *Id.* at 51.

It is also identified as "a strong inducer of phase I enzymes in rodents and co-genotoxicant in vitro in human derived cells in rather low doses, suggesting that exposure to musk ketone might increase the susceptibility to health hazards caused by carcinogens in humans."[154]

- **Myroxylon Pereirae (Balsam peru) Oil**: Defendants dramatize a simple misunderstanding regarding the distinction between balsam peru *crude* and balsam peru *extract/distillate*—a misunderstanding prompted by J&J's use of the phrase "balsam peru oil" in its documents. Dr. Crowley easily explained the issue at his deposition—both balsam peru crude and balsam peru extract/distillate have the same CAS (Chemical Abstracts Service) number.[155] Dr. Crowley used CAS numbers as part of his process of identifying and researching the chemicals. However, Dr. Crowley had no way of knowing with absolute certainty whether J&J's use of the phrase "balsam peru oil" refers to the crude or extract/distillate version: **Q**. "And what you know is that Peru balsam crude is not the ingredient that is in the *Baby Powder* or *Shower-to-Shower* powder. Correct? **A**. I don't know that."[156] Dr. Crowley ultimately testified that he takes J&J at its word that the "restricted" balsam peru extract/distillate is used in J&J *Baby Powder* rather than the "prohibited" balsam peru crude.[157] However, this issue does not affect or change Dr. Crowley's overall opinions about the fragrance chemicals used in the J&J's Talcum Powder Products.[158]

These references provide a reliable foundation for Dr. Crowley's opinions regarding the fragrance chemicals used in J&J Talcum Powder Products. The

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[154] *Id.* at 51 (citing Schmeiser, Gminski, & Mersch-Sundermann, 2001).
[155] Crowley Dep. at 171:23–172:3.
[156] *Id.* at 170:18–23.
[157] *Id.* at 172:5–173:3.
[158] Further, any disagreements over Dr. Crowley's report should be addressed in cross examination, not result in the wholesale exclusion of his opinions. "Indeed, federal courts have generally found that 'the perceived flaws' in an expert's testimony often should be treated as 'matters properly to be tested in the crucible of the adversarial system, 'not as 'the basis for truncating that process.'" *Violas v. GMC*, 73 F. Supp. 2d 452, 462 (D.N.J. 1999) (*quoting Walker v. Yellow Freight Sys., Inc.*, Civ. A. No. 98-3565, 1999 WL 757022, at *8 (E.D. La. Sep. 24, 1999)).

evidence is laid out in detail in his report—particularly in Appendices A and B—and was explained in even greater detail at his deposition. J&J's strained attempt to characterize Dr. Crowley's review as "haphazard" rests solely on J&J's own misunderstanding of certain chemical classifications (i.e. styrene), disregard for data that doesn't support J&J's position, and nit-picking at minor discrepancies. J&J has not established that Dr. Crowley "lacks good grounds" for his opinions, and they should not be excluded on that basis.

4. There is ample scientific evidence linking the fragrance chemicals used in J&J Talcum Powder Products to cancer, including ovarian cancer.

Dr. Crowley provides substantial and compelling evidence that the fragrance chemicals can contribute to the inflammatory, toxic, and carcinogenic properties of the Talcum Powder Products. Still, Defendants attempt to discount this by emphasizing that there are no *human* studies examining the chemicals' impact on *human ovaries*. But of course, it is not ethically possible to test for the carcinogenicity and toxicity of chemicals on human ovaries—studies can *only* be performed on animals. Dr. Crowley explained this repeatedly at his deposition:

- "And you don't do those kind of studies against humans. They're unethical. Right? So the safety of d-limonene has not been established in human vaginas."[159]
- "Just so we're clear, it's unethical to infuse human ovaries with para-cresol or

[159] Crowley Dep. at 222:4–7.

any of these. That's just not done."[160]

- "I don't think that any regulatory authority in the world would allow me to administer para-cresol to a human ovary. It wouldn't happen."[161]
- Regarding p-cresol studies in humans: "So to make that assertation in humans is not ethically possible. Those studies are done in animals."[162]
- Regarding p-cresol studies: "All three of those studies are done with cell lines. They are in vitro, because we don't ethically endanger humans . . . ."[163]
- Regarding styrene studies in humans: "Yeah, so as we've talked about, those studies are unethical, and that's why there aren't any."[164]

These ethical considerations require experts to rely in large part on animal studies for assessing the possible toxicity and/or carcinogenicity of chemicals—and the animal studies linking the specific fragrance chemicals in J&J's Talcum Powder Products to cancer (including the ovaries) are numerous. Dr. Crowley identifies the studies in his report, and he also listed the fragrance chemicals in *Baby Powder* that have specifically been linked to *ovarian* abnormalities in animal studies at his deposition:

- "So benzaldehyde, sister chromatid exchange, which is a mutation, in Chinese hamster *ovary cells*. That was published by Galloway in '87."[165]
- "Ethyl methylphenylglycidate sister chromatid exchange and chromosomal aberrations in Chinese hamster *ovary cells*, Galloway, 1987. European Food Safety Authority, same substance. There's substantial evidence of a genotoxic

[160] *Id.* at 282:9–12.
[161] *Id.* at 283:17–20.
[162] *Id.* at 283:23–284:1.
[163] *Id.* at 285:21–23.
[164] *Id.* at 364:13–15.
[165] *Id.* at 115:14–17 (emphasis added); *see also* Crowley Report at 22.

potential from the available in vitro and in vivo studies."[166]

- "Eugenol, sister chromatid exchange and chromosomal aberrations in Chinese hamster *ovary cells*, Galloway, 1987."[167]
- "Styrax oil, sister chromatid exchange in Chinese hamster *ovary cells*, Gulati, Witt, Anderson, Zeiger & Shelby, 1989."[168]
- "para-Cresol, cytogenetic in Chinese hamster *ovary cells*, DNA damage in human lymphocytes, morphologic transformations in mice, RTECS, the Cosmetic Ingredient Review Panel, 2006."[169]
- "para-Cymene, cytotoxic against Chinese hamster *ovary cells*."[170]
- "Propanedioic acid, diethyl ester, tumorigenic in mice following oral dosing, RTECS."[171]

Dr. Crowley had good grounds to extrapolate from those animal studies the probable effects on humans.

And while it is not ethically possible to expose human beings and/or human ovaries to potentially toxic and/or carcinogenic chemicals, studies do exist demonstrating a link between some of the fragrance chemicals in J&J's Talcum Powder Products and toxicity and/or carcinogenicity in humans. For example, counsel for J&J asked Dr. Crowley at his deposition if he was aware of any such study in humans with respect to p-cresol or para-cresol. Dr. Crowley cited a 2006

[166] Crowley Dep. at 118:3–10 (emphasis added).
[167] *Id.* at 118:11–13 (emphasis added).
[168] *Id.* at 118:14–17 (emphasis added).
[169] *Id.* at 118:18–22 (emphasis added).
[170] *Id.* at 119:3–4 (emphasis added).
[171] *Id.* at 119:6–8.

study from The International Journal of Toxicology: "The safety of Cresols was reviewed by the World Health Organization in 1995. The WHO report concluded there is clear evidence in humans that during dermal or oral exposure, high concentrations of Cresols are corrosive, absorb rapidly, and produce severe toxicity that may result in death."[172] Other examples of studies looking at human exposure include:

- Lavandula Angustifolia (Lavender) Oil: This study has demonstrated that lavender oil is cytotoxic to *human skin cells in vitro* (endothelial cells and fibroblasts) at a concentration of 0.25% (v/v) in all cell types tested (HMEC-1, HNDF and 153BR) (Prashar, Locke, & Evans, 2004).[173]

- P-cresol: "Cytogenetic in Chinese Hamster Ovary cells, DNA Damage in *human lymphocytes*, and morphologic transformation in mouse fibroblast (RTECS)."[174]

- P-cresol: "*Women exposed in their workplace* (enamel-insulated wire manufacturing) to varnishes that contained Mixed Cresols (amount not stated) had *increased gynecological problems* such as menstrual disorders and hormonal disturbances. An increased frequency of *perinatal mortality and abnormal development of newborn infants* was also reported Syrowadko and Malysheva (1977) (Syrowadko & Malysheva, 1977)."[175]

Dr. Crowley states in his report that while animal studies are not completely definitive as to whether the same effects will be observed in humans, they are

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[172] *Id.* at 284:13–23; **Exhibit 49**, Am. Coll. of Toxicology, *Final Report on the Safety Assessment of Sodium p-Chloro-m-Cresol, p-Chloro-m-Cresol, Chlorothymol, Mixed Cresols, m-Cresol, o-Cresol, p-Cresol, Isopropyl Cresols, Thymol, o-Cymen-5-ol, and Carvacrol*, 25 INT'L J. OF TOXICOLOGY 29 (2006).
[173] Crowley Report at 24 (emphasis added).
[174] Id. at 25 (emphasis added).
[175] *Id.* at 26 (emphasis added).

indicators of biological activity.[176] He testified that IARC considers both human (when available) and animal studies when classifying chemicals.[177] But, the "absence of human studies" does not mean "that somehow these [chemicals] are safe. That's not the conclusion that a person of skill in the art would conclude."[178] In other words, someone in the business of assessing chemicals for use in consumer products like Dr. Crowley would not determine that a chemical is safe for human use simply because *no human studies exist* saying otherwise—and particularly not when *numerous* animal studies exist demonstrating that the chemical has toxic and/or carcinogenic properties and when those studies are "indicators of biological activity." Dr. Crowley explained that the established biological activity or biological mechanism for both the initiation and progression of cancer here is *inflammation*. "I have found studies that link inflammation to cancer. That's an established link. That's indisputable. The Canadians stated as much in their assessment on perineal application of talc, and these fragrance chemicals are part of that product."[179]

The scientific evidence presented in the animal studies establish good grounds to support Dr. Crowley's conclusion that the fragrance chemicals raise regulatory concerns and can contribute to the inflammatory properties, toxicity, and/or potential

[176] *Id.* at 48.
[177] Crowley Dep. at 261:14–17.
[178] *Id.* at 274:2–8.
[179] *Id.* at 308:2–7.

carcinogenicity of J&J's Talcum Powder Products as a whole.

5. It was not necessary for Dr. Crowley to consider dose response to form his opinions about the fragrance chemicals in J&J Talcum Powder Products.

Defendants argue that Dr. Crowley's opinions are flawed because he did not conduct a "dose-response assessment." This argument fails for several reasons. *First*, Dr. Crowley testified that even assuming *arguendo* it was necessary to do a dose-response assessment – and it is not[180] – he could not because Defendants did not supply the necessary information for such an analysis.[181] Defendants now suggests that it would have been appropriate for Dr. Crowley to "roughly estimate" the amount of each individual chemical in *Baby Powder* and *Shower to Shower* and use "relative portions" to perform dose assessments.

Defendants provided limited, incomplete information about the fragrance chemicals in J&J's products. For example, J&J's fragrance composition documents do not specify the precise amount of each individual chemical in the products, but only "relative portions." J&J also fails to explain whether the "relative portions" of each chemical remained uniform over the many decades that the products have been on the market. It is absurd for Defendants to suggest that Dr. Crowley was required

[180] *See In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.,* 509 F. Supp. 3d at 179 ("a strong dose-response is not necessarily required for an expert to find a causal nexus.") (citing *Ferguson*, 2002 WL 34355958 at *6).
[181] *See, e.g.*, Crowley Dep. at 201:3–5, 302:14–18, 309:18–20.

to conduct a dose-response assessment after failing to provide him with *all of the information* he would need to do so in a scientifically sound and accurate manner. Dr. Crowley explained why it is not appropriate to hazard a guess about dosage and exposure, particularly when Defendants did not provide him with the information necessary to undertake such an analysis:

> So, for example, cinnamal has a Category 5 restriction of 0.05 percent. Since I don't know how much is present, I can't make a judgment as to whether the cinnamal present in *Baby Powder* exceeds 0.05 percent or not. There's a bunch of other fragrance chemicals here too that have these restrictions similar to *Shower to Shower*. Let's save each other some time. I can't make that judgment because your client hasn't given me the information to be able to do that."[182]

Regardless, Dr. Crowley did not need to conduct a dose-response assessment on the fragrance chemicals for the same reasons discussed above regarding heavy metals. Dr. Crowley is not offering a causation opinion regarding whether exposure to the individual chemicals causes ovarian cancer. He is opining as to whether those chemicals—based on all available data and studies—can contribute to the inflammatory properties, toxicity, and/or carcinogenicity *of J&J's Talcum Powder Products as a whole*. Again, the proper methodology for mixtures is a non-threshold model with consideration given to the additive effects of the components. A qualitative analysis is appropriate for mixtures, particularly where there is inadequate quantitative data available (or provided by J&J) and exposures of

[182] *Id.* at 330:15–331:2.

individual components cannot be characterized with confidence. And like the heavy metals discussed above, the many studies and data compiled by Dr. Crowley about the fragrance chemicals in J&J's Talcum Powder Products establish a biologically plausible mode of action/mechanism for the promotion of carcinogenesis:

> I mean, I've stated fairly clearly, I feel, that . . . you've got a whole bunch of irritants, you've got a whole bunch of sensitizers, and you've got a whole bunch of allergens that have been glued to talc particles, administered to the peritoneal area, which subsequently enters the vagina, and where that talc particle goes, those fragrance chemicals go with it. They have demonstrated—many of them— *demonstrated biological activity in animal and in vitro cell models that demonstrates toxicity and carcinogenicity*. And so . . . I don't know how else to state it. I think *they can absolutely contribute to the carcinogenicity of the product in total*.[183]

Dr. Crowley repeatedly explained that inflammation is a well-established biologic mechanism for both the initiation and progression of cancer, including ovarian cancer:

- "But also . . . those inflammatory chemicals travel throughout the human body. So increased levels of inflammation have been associated with a higher risk of cancers."[184]
- "I have found studies that link inflammation to cancer. That's an established link. That's indisputable. The Canadians stated as much in their assessment on perineal application of talc, and these fragrance chemicals are part of that product."[185]
- "I can also point you to the Canadian assessment on the safety of talc where they also stated that chronic inflammation and oxidative stress are important factors in the development and behavior of cancer, *including*

[183] *Id.* at 327:20–328:13 (emphasis added).
[184] *Id.* at 82:18–22.
[185] *Id.* at 308:2–7.

ovarian cancer."[186]

Dr. Crowley further explained that performing a dose-response assessment of the individual fragrance chemicals in a mixture would be problematic because it wouldn't take into consideration additive effects—that is, chemicals in combination with one another can and do behave differently than they behave individually: "Another consideration is . . . the safety studies are usually single ingredient safety studies . . . if we were to do a safety study of para-Cresol in an animal, it would be simply that. It wouldn't be para-Cresol and another 142 other chemicals. Right? So very likely there's additive effects."[187] Dr. Plunkett similarly explained: "when you have a complex mixture that has added to it things like asbestos and heavy metals, because I talk about the *additivity issue that can come to play* . . . in other words, [there is an] increased risk when you have a complex mixture with additional components that all share the same toxic properties as far as target organs or types of effects or mechanisms that are triggered in the body."[188]

For example, at least one of the fragrance chemicals in J&J's Talcum Powder Products—p-cresol—is "co-carcinogenic," which means it has been found to "promote tumors in animals when co-administered with a known carcinogen."[189]

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[186] *Id.* at 310:5–11 (emphasis added).
[187] *Id.* at 355:19–356:2.
[188] Plunkett Dep. at 146:11–21 (emphasis added).
[189] Crowley Dep. at 212:9–13; Crowley Report at 21.

This is an extremely important point when it comes to assessing mixtures—even a chemical that may not itself be classified as a known carcinogen *can increase a carcinogen's activity* when they are administered together.[190] Assessing dose response for each individual component of mixtures like fragrances (or J&J's Talcum Powder Products themselves) would not provide a complete or accurate account of the mixture's *total* inflammatory, toxic, and/or carcinogenic effects.

Finally, Dr. Crowley explained that dose response is immaterial with respect to genotoxic materials—"genotoxic materials do not live under a dose response relationship. If it's been classified as genotoxic, one molecule is enough to cause an increase in risk associated with that particular compound."[191] Dr. Crowley identified several genotoxic and potentially genotoxic fragrance chemicals in his report, including: linalyl acetate;[192] citral;[193] diethyl phthalate;[194] Ethyl Methylphenylglycidate;[195] and benzaldehyde.[196] Additionally, at least one of the

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[190] *Id.* at 361:9–13.
[191] *Id.* at 131:22–132:3.
[192] Crowley Report at 25 ("The genotoxicity of linalyl acetate described here in mammalian cells strengthens the data obtained in the bacterial ones and highlights the need of in vivo studies.").
[193] *Id.* at 23 ("Valid genotoxicity (induction of sister chromatid exchange) result in Chinese hamster ovary cells…).
[194] *Id.* at 48 ("Diethyl Phthalate, a non-fragrance present as a component in the fragrance mixture, is a phthalate ester which are reported to be endocrine disruptors, cause reproductive and developmental toxicities, and potentially genotoxic.").
[195] *Id.* at 24 ("There is substantial evidence of a genotoxic potential from the available in vitro and in vivo studies.").
[196] *Id.* at 22 ("May have a significant genotoxic effect").

fragrance chemicals—styrene—has a known genotoxic metabolite: "Styrene-7,8-oxide has been implicated and found to be carcinogenic and genotoxic in virtually every study that has ever been done with it. Metabolism of styrene to those metabolites have also been demonstrated both in humans and in animals to be carcinogenic."[197] A threshold approach based on dose response is not appropriate for genotoxic materials because "They don't have a threshold. One molecule is enough to cause an increased risk."[198]

For these reasons, Dr. Crowley's opinions should not be excluded simply because he did not perform a dose-response assessment.

III. CONCLUSION

Defendants' *Motion To Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances In Johnson's Baby Powder and Shower to Shower* should be denied. The PSC's experts' opinions regarding the heavy metals and fragrance chemical present in Johnson's *Baby Powder* and *Shower to Shower* are well-founded and reliable, and the opinions should be admitted at trial.

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Respectfully submitted,

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[197] Crowley Dep. at 255:7–13.
[198] *Id.* at 125:20–126:1.

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